JUL 11 2003

510(k) Premarket Notification
Cook Gastric Sizing Balloon Catheter
COOK INCORPORATED

Safety and Effectiveness Information

Submitted By: Carol Zwissler
Regulatory Affairs Coordinator
COOK INCORPORATED
750 Daniels Way
PO Box 489
Bloomington, IN 47402
(812) 339-2235
March 11, 2003

Device:

Trade Name:	Cook Gastric Sizing Balloon Catheter (KNT)
Proposed Classification Name:	Gastrointestinal Tube and Accessories

Predicate Device: The Cook Gastric Sizing Balloon Catheter is similar in terms of intended use, materials of construction and technological characteristics to the Gastric Balloon Suction Catheter marketed by BioEnterics.

Device Description:

The Cook Gastric Sizing Balloon Catheter is a flexible gastric tube designed to be used in gastric and bariatric surgical procedures. The catheter provides visible and tactile delineation of the cardia of the stomach along with the ability to decompress the stomach, drain and remove gastric fluid and size a gastric pouch. The silicone catheter is 18 French and 55cm long with centimeter markings every centimeter from 10cm to 50cm.

Indications for Use:

The Cook Gastric Sizing Balloon Catheter is indicated for use in gastric and bariatric surgical procedures to size the gastric pouch and drain and remove gastric fluid.

K030841

Substantial Equivalence

The Cook Gastric Sizing Balloon Catheter is similar to another gastric balloon: the Gastric Balloon Suction Catheter, marketed by BioEnterics, which was found substantially equivalent under DC# K002838.

The similar indications for use, materials of construction and the technological characteristics of the Cook Gastric Sizing Balloon Catheter as compared to the predicate device support a determination of substantial equivalency.

Test Data

The Cook Gastric Sizing Balloon Catheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests include:

- Analysis of Cuff Burst Volume
- Analysis of Cuff Diameter Over Time
- Analysis of Cuff Pressure and Diameter at Various Inflation Volumes
- Biocompatibility

The results of these tests provide reasonable assurance that the Cook Gastric Sizing Balloon Catheter has been designed and tested to assure conformance to the requirements for it use as a gastric sizing balloon.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2003

Ms. Carol Zwissler
Regulatory Affairs Coordinator
Cook Incorporated
P.O. Box 489
BLOOMINGTON IN 47402-0489

Re: K030841
Trade/Device Name: Gastric Sizing Balloon Catheter
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: June 17, 2003
Received: June 18, 2003

Dear Ms. Zwissler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Premarket Notification
Cook Gastric Sizing Balloon Catheter
COOK INCORPORATED

Device Name: Gastric Sizing Balloon Catheter

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use V OR Over-the-Counter-Use
(Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030841